IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Lorincz, A. et al. Group Art Unit: TBA

CONTINUATION of
Serial No. : 08/183,154 Examiner: TBA

Filed : January 18, 1994

For : **NON-RADIOACTIVE HYBRIDIZATION ASSAY AND KIT**

PRELIMINARY AMENDMENT

Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

Dear Sir:

Prior to examination and calculation of the filing fee, please amend the application as follows.

IN THE CLAIMS

Please cancel claim 1 and add the following new claims.

28. (new) A non-radioactive hybridization assay for the detection of a target nucleic acid sequence in a biological sample the improvement comprising the steps of:

a) hybridizing a nucleic acid sequence in a hydrolyzed sample of cells to a complementary nucleic acid probe to form a double-stranded RNA/DNA hybrid;

b) capturing the hybrid onto a solid phase to which an anti-hybrid antibody or functional anti-hybrid fragment has been immobilized, wherein the antibody or antibody fragment specifically binds to a component of the double-stranded RNA/DNA hybrid forming a bound hybrid;

c) eliminating any non-hybridized probe; and

d) detecting the bound hybrid.

29. (new) The assay of claim 28 wherein the non-hybridized probe is eliminated by digestion with an enzyme.

30. (new) The assay of claim 28 wherein the concentration of probe is between 1 and 500 ng/ml.

31. (new) The assay of claim.28 wherein the concentration of probe is between 20 and 200 ng/ml.

32. (new) The assay of claim 28 wherein the concentration of probe is approximately 75 ng/ml.

33. (new) A solution hybridization kit for the detection of a target nucleic acid sequence for diagnosing genetic defects, microbial or viral infections in a biological sample with an accuracy of at least 89% comprising:

a) a sample transport medium for stabilization of the biological sample;

b) a probe complementary to the target nucleic acid sequence for formation of a double-stranded RNA/DNA hybrid;

c) a solid phase to which an anti-hybrid antibody or a functional anti-hybrid antibody fragment has been immobilized, wherein the antibody or antibody fragment specifically binds to a component of the double-stranded RNA/DNA hybrid; and

d) means for detecting the hybrid formed by hybridization of the probe and the target nucleic acid sequence.

REMARKS

Applicants respectfully request favorable consideration of the present application and claims. The newly added claims are supported by the original specification and do not introduce any new matter. Early and favorable action by the Examiner is earnestly solicited.

No additional fee is believed to be necessary.

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2629-4023.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition and for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2629-4023

A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

Date: May 7, 2001

By: _____
Dorothy R. Auth
Registration No. 36,434

MORGAN & FINNEGAN, L.L.P.
345 Park Ave
New York, NY 10154-0053
(212)-758-4800 Telephone
(212)-751-6849 Facsimile

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Lorincz, A. et al. Group Art Unit: TBA

CONTINUATION of
Serial No. : 08/183,154 Examiner: TBA

Filed : January 18, 1994

For : **NON-RADIOACTIVE HYBRIDIZATION ASSAY AND KIT**

PRELIMINARY AMENDMENT

Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

Dear Sir:

Prior to examination and calculation of the filing fee, please amend the application as follows.

IN THE CLAIMS

Please cancel claim 1 and add the following new claims.

28. (new) A non-radioactive hybridization assay for the detection of a target nucleic acid sequence in a biological sample the improvement comprising the steps of:

a) hybridizing a nucleic acid sequence in a hydrolyzed sample of cells to a complementary nucleic acid probe to form a double-stranded RNA/DNA hybrid;

b) capturing the hybrid onto a solid phase to which an anti-hybrid antibody or functional anti-hybrid fragment has been immobilized, wherein the antibody or antibody fragment specifically binds to a component of the double-stranded RNA/DNA hybrid forming a bound hybrid;

c) eliminating any non-hybridized probe; and

d) detecting the bound hybrid.

29. (new) The assay of claim 28 wherein the non-hybridized probe is eliminated by digestion with an enzyme.

30. (new) The assay of claim 28 wherein the concentration of probe is between 1 and 500 ng/ml.

31. (new) The assay of claim.28 wherein the concentration of probe is between 20 and 200 ng/ml.

32. (new) The assay of claim 28 wherein the concentration of probe is approximately 75 ng/ml.

33. (new) A solution hybridization kit for the detection of a target nucleic acid sequence for diagnosing genetic defects, microbial or viral infections in a biological sample with an accuracy of at least 89% comprising:

a) a sample transport medium for stabilization of the biological sample;

b) a probe complementary to the target nucleic acid sequence for formation of a double-stranded RNA/DNA hybrid;

c) a solid phase to which an anti-hybrid antibody or a functional anti-hybrid antibody fragment has been immobilized, wherein the antibody or antibody fragment specifically binds to a component of the double-stranded RNA/DNA hybrid; and

d) means for detecting the hybrid formed by hybridization of the probe and the target nucleic acid sequence.

REMARKS

Applicants respectfully request favorable consideration of the present application and claims. The newly added claims are supported by the original specification and do not introduce any new matter. Early and favorable action by the Examiner is earnestly solicited.

No additional fee is believed to be necessary.

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2629-4023.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition and for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2629-4023 A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

Date: May 7, 2001

By: _____
Dorothy R. Auth
Registration No. 36,434

MORGAN & FINNEGAN, L.L.P.
345 Park Ave
New York, NY 10154-0053
(212)-758-4800 Telephone
(212)-751-6849 Facsimile